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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Patent Application of

Deborah Kim GLENCROSS

Application No.: 10/754,711

Filing Date: January 12, 2004

Title: ENUMERATION OF CD4+  
LYMPHOCYTES (AS AMENDED)

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)  
) Group Art Unit: 1651  
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) Examiner: A. FORD  
)  
) Confirmation No.: 1340  
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FIRST  
INFORMATION DISCLOSURE STATEMENT  
TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed is a FIRST Information Disclosure Statement (IDS) Form PTO-1449 and 18 Cited References for the above-identified patent application.

- ☐ No additional fee for submission of an IDS is required.
- ☐ The fee of 180 as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e), and the fee of 180 as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge \_\_\_\_\_ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the fee due.
- ☐ Charge \_\_\_\_\_ to credit card for the fee due. Form PTO-2038 is attached.
- ☒ The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BUCHANAN INGERSOLL AND ROONEY PC

Date December 7, 2006

By:

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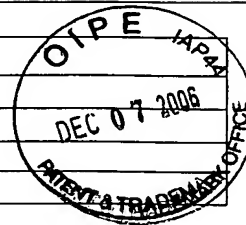


**FIRST**  
**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Application Number	10/754,711
Filing Date	January 12, 2004
First Named Inventor	Deborah Kim GLENCROSS
Examiner Name	A. FORD
Attorney Docket No.	1025455-000113



**U.S. PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	STATUS						
					Translation	Partial Translation	Eng. Lang. Summary	Search Report	IPER	Abstract	Cited in Spec

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Ian Storie et al., "Flow Rate Calibration II: A Clinical Evaluation Study Using PanLeucoGating as a Single-Platform Protocol", Clinical Cytometry, 55B:8-13 (2003).
	D.K. Glencross et al., "Results from the WHO/NHLS/QASI CD4 Regional External Quality Assessment Scheme (REQAS): Multi-Site Evaluation of CD4 Technology Performance", 2 <sup>nd</sup> South African AIDS Meeting, June 2005.
	W. Stevens et al., "Affordable HIV Diagnosis and Monitoring for Scaling Up ARV Treatment Programmes", The Southern African Journal of HIV Medicine, September 2005, pages 38-41.
	L. Scott et al., "Monitoring Reproducibility of Single Analysis, Single Platform CD4 Cell Counts in a High Volume, Low Resource Laboratory Setting Using Sequential Bead Count Rates", Clinical Cytometry, 67B:31-32 (2005).

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**FIRST**  
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(use as many sheets as necessary)

Sheet 2 of 2

Application Number	10/754,711
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Attorney Docket No.	1025455-000113

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	T. Rehle et al., "HIV-positive educators in South African public schools", Education Labour Relations Council, 2005.
	T. Rehle et al., "Appendix and Addenda - HIV-positive educators in South African public schools", Education Labour Relations Council, 2005.
	NCCLS, "Clinical Applications of Flow Cytometry: Quality Assurance and Immunophenotyping of Lymphocytes; Approved Guideline", 1998.
	U.S. Food and Drug Administration, "Recognized Consensus Standards", <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.CFM?Standard_identification_NO-10448">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.CFM?Standard_identification_NO-10448</a> .
	G. Vercauteren et al., "Impact of Who External Quality Assessment (EQA) programme on the laboratory performance of CD4 enumeration for monitoring of ARV therapy in Resource Limited settings", World Health Organization, Conference: AIDS2006 (Abstract).
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Examiner Signature		Date Considered	
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